

## REMARKS

The Office Action of January 29, 2009 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection are traversed and overcome. Upon entry of this Amendment, claims 1, 7-14, 16-18 and 20 remain in the application. New claim 21 has been added. Claims 11-14, 16, and 17 have been withdrawn. Claim 6 is cancelled herein and claims 2-5, 15 and 19 were previously cancelled. At least the independent claims have been amended herein. Support for the amendments to the various claims can be found throughout the application as filed, at least on page 9, lines 15-22; from page 10, line 8 to page 11, line 2; from page 11, line 11 to page 12, line 8, and in cancelled claim 6. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claim 1, 6, 7, 18 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Groll (U.S. Patent Application Publication No. 2005/0019953) in view of Burke et al. (U.S. Patent Application Publication No. 2008/0098802) and Ward (U.S. Patent No. 5,410,504). Claims 8-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Groll in view of Burke and Ward, as applied to claim 1 above, and further in view of Mandecki (U.S. Patent Application Publication No. 2002/0006673).

As amended, Applicants' invention as recited in claim 1 and in the other independent claims relates to a self-calibrating, disposable blood test device and to a single, self-calibrating, disposable test strip. Each independent claim recites in some form: a substrate configured for carrying a chemical reagent; and circuitry formed on the substrate. The circuitry includes at least: an information storage portion configured to store information indicative of at least one calibration value of the chemical reagent for calibrating operation of a meter to accurately measure and monitor a test of the blood analyte; and an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the at least one calibration value from the information storage portion. No other source of calibration information separate from the information storage portion on the disposable blood test device is used for calibration of the meter. The information

storage portion includes at least one electrically conductive element including a plurality of impedance elements. Each impedance element is configured to be physically altered by at least one of punching, drilling, and shorting via fusible link. A number,  $N$ , of the impedance elements in a determinable order produces characteristic impedance that is indicative of the at least one calibration value of the chemical reagent. The  $N$  impedance elements produce  $2^N$  different possible calibration values. The plurality of impedance elements includes at least one of: a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel.

In contrast, the combination of Groll, Burke and Ward does not teach or suggest the Applicants' invention as defined in the pending claims. Groll discloses "information contact pads" that are coded with information by the use of laser ablation techniques. Groll does not teach or suggest that these laser-ablated "information contact pads" produce a change in impedance in the system which could be interpreted as calibration information. Rather, Groll's information contact pads are coded and read conventionally according to the presence or absence of a conductive layer in a particular area of the substrate. (See Groll, paragraph [0077]). Groll does not teach or suggest impedance elements on a substrate which are configured to be physically altered by punching, drilling, and/or shorting via fusible link, and which can then convey specific calibration information to the system via their change in impedance. Furthermore, Groll does not teach or suggest the exponentially varied  $2^N$  number of possible calibration values that can be obtained from the  $N$  impedance elements of the Applicants' invention as defined in the pending claims. The possible number of pieces of information that can be coded on the substrate by the coding system of Groll's contact pads is starkly more limited.

Furthermore, Burke's disclosure relates to the fact that impedance can be determined when both DC and AC responses are measured simultaneously as blood is tested in a glucose meter. Burke teaches that the impedance value that is determined from the DC and AC responses can then be used to correct for the effects of interferants in the DC measurement. Thus, unlike the Applicants' invention as defined in the pending claims, Burke does not teach or suggest actual impedance elements

physically existing on the substrate surface which contain specific calibration information coded therein, where such information is read by the system to calibrate measurements in the system. Still further, it is submitted that Burke neither teaches nor suggests a  $2^N$  number of calibration values produced by impedance elements. Rather, Burke discloses only that the determination of impedance during the course of measuring glucose in blood by a glucose meter can be useful to increase the accuracy of measurements in the glucose meter. As mentioned above, Burke also discloses examples of how such impedance measurements can be obtained from conventional glucose meter measurements by measuring DC and AC response simultaneously. (See Burke, paragraphs [0065]-[0068]).

As is evident from the discussions above, the combination of Burke with Groll does not teach or suggest anything about impedance elements on the substrate, a  $2^N$  number of calibration values produced by the impedance elements, or that these impedance elements may be physically altered, specifically by punching, drilling, and/or shorting via fusible link. All of these aspects of the Applicants' invention as defined in the pending claims contribute to the obtaining of a potentially large amount of calibration information regarding chemical reagents on the substrate. All of these aspects are neither taught nor suggested by the combination of Burke with Groll.

With regard to the above § 103(a) rejection of claims 1, 6, 7, 18 and 20, the addition of Ward to the combination of Burke and Groll fails to supply the deficiencies of Burke and Groll described above.

Furthermore, with regard to the §103(a) rejection of claims 8-10, the addition of Mandecki to the combination of Ward, Burke and Groll fails to supply the deficiencies of Ward, Burke and Groll described above.

For all the reasons stated above, it is submitted that Applicants' invention as defined in the independent claims, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by any combination of the cited references, either alone or in combination, and patentably defines over the art of record.

It is submitted that if claim 1 is found to contain allowable subject matter, it is requested that the Examiner also consider claims 11-14, 16, and 17 for rejoinder. Claims 11-14, 16, and 17 are method of manufacturing claims which require all of the limitations of the test device as defined in claim 1. Thus, under the requirements of MPEP §821.04(b), claims 11-14, 16, and 17 are eligible for rejoinder, and the previous restriction requirement of claims 11-14, 16, and 17 should be withdrawn.

In summary, claims 1, 7-14, 16-18, 20 and 21 remain in the application. It is submitted that, through this Amendment, Applicants' invention as set forth in these claims is now in a condition suitable for allowance.

Further and favorable consideration is requested. If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact Applicants' Attorney at the below-listed telephone number.

Respectfully submitted,

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